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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,337	09/18/2003	John E. Nash	KN P 0125	5437
42016 7590 01/02/2008 KENSEY NASH CORPORATION 735 PENNSYLVANIA DRIVE EXTON, PA 19341			EXAMINER TRUONG, KEVIN THAO	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 01/02/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/665,337

Applicant(s)

NASH ET AL.

Examiner

Kevin T. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/06/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Note: This is in response to amendment filed 11/06/2007.

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 73 and 77-79 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 35, 38 and 42-44 of prior U.S. Patent No. 6,080,170. This is a double patenting rejection.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-89 of U.S. Patent No. 6,905,505.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively subject matter claimed in the instant application such as a device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second and higher flow rate to create a differential flow in said lumen, whereupon at least a portion of any debris produced by the operation of said working head is thereby withdrawn by said at least one helical pump through said passageway for collection remote from the occluded vessel portion and is thereby prevented from flowing into any upstream blood vessel or downstream blood

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vessel. These limitations would have been obvious in view of the relatively subject matter of the patent claims.

3. Claims 1-72 and 83-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 and 36-37 of U.S. Patent No. 6,080,170. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively subject matter claimed in the instant application such as a device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second and higher flow rate to create a differential flow in said lumen, whereupon at least a portion of any debris produced by the operation of said working head is thereby withdrawn by said at least one helical pump through said passageway for collection remote from the occluded vessel portion

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and is thereby prevented from flowing into any upstream blood vessel or downstream blood vessel. These limitations would have been obvious in view of the relatively subject matter of the patent claims.

4. Claims 1-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent No. 5,879,361.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively subject matter claimed in the instant application such as a device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second and higher flow rate to create a differential flow in said lumen, whereupon at least a portion of any debris produced by the operation of said working head is thereby withdrawn by said at least one helical pump

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through said passageway for collection remote from the occluded vessel portion and is thereby prevented from flowing into any upstream blood vessel or downstream blood vessel. These limitations would have been obvious in view of the relatively subject matter of the patent claims.

5. Claims 1-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 5,779,721.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively subject matter claimed in the instant application such as a device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second and higher flow rate to create a differential flow in said lumen, whereupon at least a portion of any debris produced by the

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operation of said working head is thereby withdrawn by said at least one helical pump through said passageway for collection remote from the occluded vessel portion and is thereby prevented from flowing into any upstream blood vessel or downstream blood vessel. These limitations would have been obvious in view of the relatively subject matter of the patent claims.

6. Claims 1-72 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,524,323.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively subject matter claimed in the instant application such as a device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working head and withdrawing said liquid at a second and higher flow rate to create a differential

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flow in said lumen, whereupon at least a portion of any debris produced by the operation of said working head is thereby withdrawn by said at least one helical pump through said passageway for collection remote from the occluded vessel portion and is thereby prevented from flowing into any upstream blood vessel or downstream blood vessel. These limitations would have been obvious in view of the relatively subject matter of the patent claims.

7. Claims 73-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,843,797. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively subject matter claimed in the instant application such as a device for treatment of a lumen in a blood vessel portion of a living being's vascular system, said device comprising an outer catheter and an instrument having an inner catheter, a working head, and pump means comprising at least one helical pump, wherein said instrument is arranged to be extended through said outer catheter to form a passageway therebetween, said working head of said instrument is arranged to operate on occlusive material in a blood vessel's interior portion to open a lumen therein for the freer flow of blood therethrough, whereupon some debris may be produced by the operation of said working head, wherein said inner catheter comprises a jacket having proximal and distal ends, and further wherein said inner catheter is flexible to permit navigation through tortuous paths of vasculature, said helical pump being disposed in said jacket in such a way as to form an annulus therebetween, said pump means being capable of introducing an infusate liquid at a first flow rate at said working

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head and withdrawing said liquid at a second and higher flow rate to create a differential flow in said lumen, whereupon at least a portion of any debris produced by the operation of said working head is thereby withdrawn by said at least one helical pump through said passageway for collection remote from the occluded vessel portion and is thereby prevented from flowing into any upstream blood vessel or downstream blood vessel. These limitations would have been obvious in view of the relatively subject matter of the patent claims.

Response to Arguments

8. Applicant's arguments filed 11/06/2007 with respect to claims 1-87 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin T. Truong whose telephone number is 571-272-4705. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Kevin T. Truong', enclosed within a large, stylized circular flourish.

Kevin T. Truong

Primary Examiner

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ktt